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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,406	FRANCISCO ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11,13-19 and 67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,13-19 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment filed on 10/02/2003 is acknowledged. Claim 11 is amended, and claim 67 is new. Claims 1-8, 11, 13-19, and 67 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 is confusing because the step (b) says that cells are added "in the presence of **only** RPMI with 10% fetal bovine serum or 20% fetal bovine serum to the well". However, it appears that an antibody of interest should also present in the well in order to test whether an anti-CD30 is cytotoxic or not.

Claim 67 recites the limitation "the well" in step (b) line 2. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 67 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection. The Office is unable to find support that Hodgkin's disease cell line is added to a well in presence of only RPMI with 10 % or 20 % FBS. The specification at page 50 at lines 19-24 does not say that Hodgkin's disease cell line is grown in RPMI with 10 % or 20 % FBS.

Claim Rejections - 35 USC § 102

Claims 1-5, 7, 8, 11, 13, 15, 16, and 19 **remain rejected** for reason of record and the new claim 67 is also rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/22384 (25 July 1996).

The claims are interpreted as drawn to method of Hodgkin's disease treatment by administering anti-CD 30 antibody alone or conjugate anti-CD antibody alone.

Applicant argues that the art teaches treatment of Hodgkin's disease using anti-CD30 antibody conjugated to toxin and HeFi-1 and C10 are different group than Ki-4; the rejection of claim 11 is moot because the amended the base claim no longer recite the limitation "SEQ ID NO:10". These arguments have been fully considered but found unpersuasive because the art teaches treatment of Hodgkin's disease using a generic anti-CD antibody (without any toxin attached) that releases soluble CD30 from Hodgkin's disease cells to an amount of less

than 10 % at the abstract and claims 13 and 14. Further, the art teaches HeFi-1 and C10 (a.k.a. AC10 according applicant's amendment at page 6, line 5 of 21st paragraph filed on 10/02/2003) at Table 2. Thus, the art teaches that any generic antibody to CD30 could be used to treat Hodgkin's disease as long as said antibody releases soluble CD30 from Hodgkin's disease cells to an amount of less than 10 %. Applicant is invited to present scientific data to the Office that HeFi-1 and C10 release more than 10 % soluble CD30 or that the various antibodies claimed in claim 1 of the art of record does not have the activity recited in the instant claims in order to obviate this rejection.

As for applicant's argument that the rejection of claim 11 is moot, the instant specification at page 29 lines 28-29 says that instant SEQ ID NO:2 is variable region of AC10 (a.k.a. C10) disclosed Table 2 at page 21 of the art. Therefore, the C10 antibody is a protein comprises an amino acid sequence that has SEQ ID NO:2.

Claim Rejections - 35 USC § 103

Claims 6, 14, 17 and 18 remain rejected for reason of record under 35 U.S.C. 103(a) as being unpatentable over WO 96/22384 as applied to claims 1-5, 7, 8, 11, 13, 15, 16, and 19 above, and further in view of Barth et al (June 2000, Blood, vol. 95, page 3909-14).

The claims are interpreted as drawn to method of Hodgkin's disease treatment by administering anti-CD 30 antibody or conjugate anti-CD antibody in combination with other known conventional chemotherapy.

Applicant argues that the primary reference WO 96/22384 does not teach antibody that is required in the base claims but this argument is not persuasive because the primary reference teaches HeFi-1 and AC10 as discussed above. Note 102 rejection above.

Double Patenting

Applicant is advised that should claim 1 be found allowable, the new claim 67 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. the specifically cited cytotoxicity measurement in new claim 67 does not affect method step and does not result in any material differences. Product and method of claim 1 and 67 are same. Only measurement of cytotoxicity is slightly differently worded. See MPEP § 706.03(k).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
January 6, 2004